

Congress of the United States
House of Representatives
Washington, DC 20515-0545

August 17, 2021

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock,

We write to request information about the Food and Drug Administration (FDA)'s plans to issue an Emergency Use Authorization (EUA) for the COVID-19 vaccine in children under 12 years of age. As transmission rates increase and schools reopen for in-person instruction, parents need to know when their kids will be able to get vaccinated.

The COVID-19 vaccines made by Pfizer-BioNTech and Moderna have been available to adults since the FDA authorized them in December 2020.¹ In May 2021, the FDA expanded the EUA for the Pfizer-BioNTech vaccine to include individuals from ages 12-15.² Children under 12 are still not eligible to receive any COVID-19 vaccination. No pharmaceutical company has applied for an EUA, and clinical studies are ongoing.³ Data from these trials was expected by September, but recent FDA requests to increase the size and scope of the studies may delay the results.⁴ The current situation is alarming for parents, including many of us, whose children ages 2-11 will be in months of school without vaccinations available.

¹ "Pfizer-BioNTech COVID-19 Vaccine." U.S. Food & Drug Administration (Jul. 23, 2021), https://www.fda.gov/emergenthttps://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.htmlncy-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine; "Moderna COVID-19 Vaccine." U.S. Food & Drug Administration (Jul. 7, 2021), <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>.

² "Coronavirus (COVID-19) Update: FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents in Another Important Action in Fight Against Pandemic." U.S. Food & Drug Administration (May 10, 2021), <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use>.

³ Sheryl Gay Stolberg, et al, "Vaccine Makers Are Asked to Expand Safety Studies on Children." The New York Times (Jul. 28, 2021), <https://www.nytimes.com/2021/07/26/us/politics/covid-vaccine-trials-children.html?action=click&module=RelatedLinks&pgtype=Article>.

⁴ The FDA asked Pfizer-BioNTech and Moderna to include at least 3,000 children between 5 and 11 in order to better detect rare side effects including heart inflammation problems. Sheryl Gay Stolberg, et al, "Vaccine Makers Are Asked to Expand Safety Studies on Children." The New York Times (Jul. 28, 2021), <https://www.nytimes.com/2021/07/26/us/politics/covid-vaccine-trials-children.html?action=click&module=RelatedLinks&pgtype=Article>.

Though children and adolescents who contract COVID-19 generally have milder symptoms than adults, more than four million Americans under age 18 have tested positive for the virus.⁵ Children— including those without symptoms— can spread COVID-19 to others, including immunocompromised and high-risk adults.⁶ And while most kids are not likely to become seriously ill, the long-term health consequences are unknown— and some children are dying of COVID-19.⁷ And as with adults, there is a much higher risk for kids with underlying conditions like type 1 diabetes or heart problems.⁸

After declining in early summer, pediatric cases have recently increased steadily, with almost 72,000 children testing positive in the last week of July 2021.⁹ This, according to the American Academy of Pediatrics (AAP) is “the largest week-over-week percentage increase in pediatric COVID-19 cases since the start of the pandemic.” The AAP also recently noted that: “In our view, the rise of the Delta variant changes the risk-benefit analysis for authorizing vaccines in children. The FDA should strongly consider authorizing these vaccines for children ages 5-11 years based on data from the initial enrolled cohort.”

In some states, the number of children hospitalized with COVID-19 is higher now than at any other point during the pandemic.¹⁰ This surge and the rise of new, more dangerous variants is coming right as the school year begins, as temperatures drop, and as more parents are required to return to in-person work.¹¹ As Brown University School of Public Health Dean Dr. Ashish K. Jha said, “given the unprecedented level of infections and hospitalizations we are seeing in kids, we need to move quickly to protect America’s children by making vaccines available as quickly as the data warrant.”

Within the next 10 days, we request a briefing from the FDA on the status of EUA for a COVID-19 vaccine for kids. At that briefing, we seek answers to the following questions:

1. When will the FDA begin studying the safety and efficacy data for children from 5-11 years old that is already publicly available?
2. When does the FDA expect to receive data from clinical trials studying the benefits and risks of vaccines for children under age 5? Will this data include information about children as young as 2?

⁵ Melissa Jenco, “Survey: Support of school COVID-19 vaccine mandates growing, resistance to vaccinating children shrinking,” American Academy of Pediatrics News (Jul. 20, 2021), <https://www.aappublications.org/news/2021/07/20/covid-vaccine-school-mandate-072021>.

⁶ “Science Brief: Transmission of SARS-CoV-2 in K-12 Schools and Early Care and Education Programs – Updated,” Centers for Disease Control and Prevention (Jul. 9, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html.

⁷ Helen Thomson, “Children with long covid,” National Center for Biotechnology Information (Feb. 27, 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7927578/>.

⁸ Jennifer E. Schuster, et al., “COVID-19 in Children—Not Just Little Adults,” Journal of the American Medical Association (Jun. 7, 2021), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2780708>.

⁹ “Children and COVID-19: State-Level Data Report,” American Academy of Pediatrics (Jul. 26, 2021), <https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/>.

¹⁰ “Children and COVID-19: State-Level Data Report,” American Academy of Pediatrics (Jul. 26, 2021), <https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/>; Jemima McEvoy, “Covid Cases Among Children Jumped 84% Last Week—Here Are The States Where Kid Hospitalizations Are Increasing,” Forbes (Aug. 4, 2021), <https://www.forbes.com/sites/jemimamcevoy/2021/08/04/covid-cases-among-children-jumped-84-last-week-here-are-the-states-where-hospitalizations-are-increasing/?sh=6718af163be9>.

¹¹ “Variants of the Virus,” Centers for Disease Control and Prevention (Aug. 4, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html>.

3. How long will it take for the FDA to review the safety and efficacy data once relevant studies are complete? What, if any, barriers or competing concerns does the FDA see to the fastest scientifically possible review of the data?
4. In determining the safety and efficacy of a COVID-19 vaccine for children, is the FDA applying the same standard of review as it applied to determining an EUA was warranted based on the safety and efficacy of the vaccine for adult use?
5. How have the studies addressed the recommended childhood vaccination schedules for non-COVID illnesses and how might this interact with safe vaccine distribution?

We recognize that the FDA must consider many factors for vaccine authorization, even for an EUA during a global pandemic. The start of the school year, however, was a clear moment that could have been used to educate and disseminate vaccines. Now with a late summer surge, the reopening of schools seems likely to increase community spread.

We respect the scientific process and the FDA's dedication to safety, and we applaud the swiftness with which the FDA granted an EUA for the COVID-19 vaccines for adults and adolescents. The American people need information about the status of an EUA for a vaccine safe for children, however, and we as lawmakers need to understand the FDA's efforts to protect our youngest Americans.

Very Truly Yours,

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CC: Ronald Klain, Chief of Staff to the President of the United States